

APR 23 1998

16981278

510(k) Summary

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
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1. Submitter name, address, contact	<p>Roche Diagnostics/Boehringer Mannheim Corporation 4300 Hacienda Drive Pleasanton, CA 94566-0900 (925) 730 - 8215 Fax number: (925) 225 - 0654</p> <p>Contact Person: Patricia M. Klimley</p> <p>Date Prepared: April 7, 1998</p>
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2. Device Name	<p>Proprietary name: Elecsys® CalCheck™ CA 125II</p> <p>Common name: Calibration Verification Material</p> <p>Classification name: Single (specified) analyte controls (assayed + unassayed)</p>
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3. Predicate device	The Roche Diagnostics/Boehringer Mannheim Corporation Elecsys® CalCheck™ CA 125II is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH.
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4. Device Description	The Roche Diagnostics/Boehringer Mannheim Corporation Elecsys CalCheck CA 125II is manufactured using human serum albumin, CA 125, stabilizers, and preservatives. The analyte is appropriately spiked into the calcheck matrix to the correct calcheck concentration levels. The calcheck are in process checked and quality controlled against ID-GC/MS.
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510(k) Summary, Continued

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| 5.
Intended use | The Roche Diagnostics/Boehringer Mannheim Corporation Elecsys® CalCheck™ CA 125II is used to verify the calibration assignment for the Roche Diagnostics/Boehringer Mannheim Corporation Elecsys CA 125II assay. |
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| 6.
Comparison
to predicate
device | <p>The Roche Diagnostics/Boehringer Mannheim Corporation Elecsys® CalCheck™ CA 125II is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® CalCheck™ TSH.</p> <p>Both products are intended to be used for the verification of calibration for analytes on automated immunoassay analyzers.</p> |
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| 7. Performance
Characteristics | The Elecsys® CalCheck™ CA 125II was evaluated for value assignment and stability. |
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 23 1998

Patricia M. Klimley
Manager, Elecsys Regulatory Affairs
Roche Diagnostics/Boehringer Mannheim Corporation
4300 Hacienda Drive
P.O. Box 9002
Pleasanton, California 94566-0900

Re: K981278
Elecsys® CalCheck™ CA 125II
Regulatory Class: I
Product Code: JJX
Dated: April 7, 1998
Received: April 8, 1998

Dear Ms. Klimley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

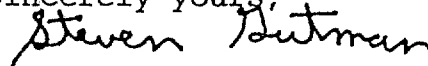
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

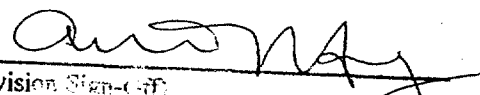
510(k) Number (if known):

Device Name: Roche Diagnostics/Boehringer Mannheim Corporation Elecsys® CalCheck™ CA 125II

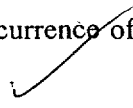
Indications For Use:

Elecsys® CalCheck™ CA 125II calibration verification solutions comprise three levels - low, mid, and high - each with a defined CA 125II concentration. The low solution concentration is near the lower detection limit of the assay. The mid solution is in the middle or at the clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys® CalCheck™ CA 125II is intended for use in periodic verification of the calibration of the Elecsys® CA 125II assay.


(Division Sign-off)
Division of Clinical Laboratory Sciences
510(k) Number K981298

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

 Concurrency of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)